fragment or an angiogenically active mutein thereof by infusion into one or more coronary vessels or into a peripheral vein in a human patient in need of treatment for coronary artery disease, said unit dose comprising from about .008 mg to 7.2 mg of said recombinant FGF-2 or said angiogenically active fragment or said angiogenically active mutein thereof.

59. (amended) The method of claim 58, wherein said recombinant FGF-2 has the amino acid sequence of SEQ ID NO: 2.

62. (amended) A method for treating a human patient for a myocardial infarction, comprising administering a single unit dose of a recombinant ~~FGF-2~~ or an angiogenically active fragment or an angiogenically active mutein thereof by infusion into one or more coronary vessels or into a peripheral vein in said human patient, said unit dose comprising from about .008 mg to 7.2 mg of said recombinant FGF-2 or said angiogenically active fragment or said angiogenically active mutein thereof.

64. (amended) The method of claim 63, wherein said recombinant FGF-2 has the amino acid sequence of SEQ ID NO: 2.

65. (amended) A method for providing a human patient with relief from symptoms of angina comprising administering a single unit dose of a recombinant ~~FGF-2~~ or an angiogenically active fragment or an angiogenically active mutein thereof by infusion into one or more coronary vessels or into a peripheral vein in a human patient in need of relief from symptoms of angina, said unit dose comprising from about 0.008 mg to 7.2 mg of said recombinant FGF-2 or said angiogenically active fragment or said angiogenically active mutein thereof.

REMARKS

Responsive to the telephone conversation with the Examiner on January 30, 2002, wherein the Examiner indicated actions and claim amendments necessary to bring the above-identified application into condition for allowance, Applicant submits herewith amendments to

the claims and a Terminal Disclaimer. As suggested by the Examiner, claims have been amended to recite the descriptive phrase "angiogenically active" before each recitation of the phrase "mutein". Support for recitation of "angiogenically active" muteins resides throughout the specification and in the pending claims. See, for example, at page 14, lines 26 and 27, at page 16, line 4, and claims 5 and 6 as originally filed. Claims 13-17, 24, 26, 30, 35, 47-51, 56, 58, 62, and 65 have been amended to provide for consistency in recitation of the modifier "said" as opposed to "a" or "an" before a particular element (i.e., recombinant FGF-2, angiogenically active fragment of the recombinant FGF-2, or angiogenically active mutein of the recombinant FGF-2) within those independent claims where the element is recited more than once, and in those dependent claims for which antecedent basis resides in the respective claim from which they depend. Claims 18, 27, 32, 52, 59, and 64 have been amended to recite "said recombinant FGF-2" to provide for consistency with the language recited in claims 11 and 45. No new matter is added by way of claim amendment, nor is the scope of these claims affected by way of these amendments.

Claims 10-67 are now pending in the application. Reexamination and reconsideration of the application are respectfully requested.

Submission of Terminal Disclaimer

The Examiner indicated that a Terminal Disclaimer over copending and coassigned U.S. Application Serial No. 09/417,721, for which a Notice of Allowability was granted on January 11, 2002, would be necessary under 37 C.F.R. §1.321(c) to bring the present application into condition for allowance. Applicant submits herewith a Terminal Disclaimer under 37 C.F.R. §1.321(c). Entry of this disclaimer into the record of the present application is respectfully requested.

Applicant wishes to thank Examiner Hope Robinson for her diligent examination of this application, including her time spent in discussions with her supervisor and with the Examiner assigned to copending U.S. Application Serial No. 09/417,721 regarding the subject matter set forth in the pending claims in this application and in the allowed claims in the 09/417,721 application.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully submits that the remaining rejections are now overcome and that this application is now in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those, which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

Leslie T. Henry

Leslie T. Henry
Registration No. 45,714

CUSTOMER NO. 00826
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Raleigh Office (919) 862-2200
Fax Raleigh Office (919) 862-2260

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to Examiner Hope Robinson at the United States Patent and Trademark Office at Fax No. (703) 308-4242 on January 31, 2002.

Polly P. Burton

Polly P. Burton

Version with Markings to Show Changes Made:

In the Claims:

Please amend claims 10, 12-18, 24, 26, 27, 30, 32, 35, 38, 44, 46-52, 56, 58, 59, 62, 64, and 65 to read as follows:

10. (twice amended) A method for treating a human patient for coronary artery disease, comprising administering a therapeutically effective amount of a recombinant FGF-2 or an angiogenically active fragment or an angiogenically active mutein thereof into one or more coronary vessels or into a peripheral vein in a human patient in need of treatment for said coronary artery disease, said therapeutically effective amount being about 0.2 μg/kg to 48 μg/kg of patient weight.

12. (amended) The method of claim 11, further comprising the step of administering to said human patient about 10 U/kg to 80 U/kg of heparin within about 0 to 30 minutes prior to administering said recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or said angiogenically active mutein thereof.

13. (twice amended) The method of claim 12, wherein said therapeutically effective amount of [a]said recombinant FGF-2 of SEQ ID NO: 2 or [an]said angiogenically active fragment or said angiogenically active mutein thereof is administered into one or more coronary vessels.

14. (amended) The method of claim 13, wherein said therapeutically effective amount of [a]said recombinant FGF-2 of SEQ ID NO: 2 or [an]said angiogenically active fragment or said angiogenically active mutein thereof is about 24 μg/kg to 48 μg/kg.

15. (twice amended) The method of claim 12 wherein said therapeutically effective amount of [a]said recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or said angiogenically active mutein thereof is administered into a peripheral vein.

16. (amended) The method of claim 15, wherein said therapeutically effective amount of [a]said recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or said angiogenically active mutein thereof is about 18 μg/kg to 36 μg/kg.

17. (twice amended) A method for treating a human patient for coronary artery disease, comprising administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or an angiogenically active mutein thereof into one or more coronary vessels or into a peripheral vein in a human patient in need of treatment for coronary artery disease, said unit dose comprising from about .008 mg to 7.2 mg of [a]said recombinant FGF-2 or [an]said angiogenically active fragment or said angiogenically active mutein thereof.

18. (amended) The method of claim 17, wherein said recombinant FGF-2 has the amino acid sequence of SEQ ID NO: 2.

24. (amended) The method of claim 20, wherein said unit dose comprises 0.3 mg to 3.5 mg of [a]said recombinant FGF-2 of SEQ ID NO: 2 or [an]said angiogenically active fragment or said angiogenically active mutein thereof.

26. (twice amended) A method for inducing angiogenesis in a heart of a human patient, comprising administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or an angiogenically active mutein thereof into one or more coronary vessels or into a peripheral vein in a human patient in need of treatment for coronary artery disease, said unit dose comprising from about .008 mg to 7.2 mg of [a]said recombinant FGF-2 or [an]said angiogenically active fragment or said angiogenically active mutein thereof.

27. (amended) The method of claim 26, wherein said recombinant FGF-2 has the amino acid sequence of SEQ ID NO: 2.

30. (twice amended) A method for treating a human patient for a myocardial infarction, comprising administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or an angiogenically active mutein thereof into one or more coronary vessels or into a peripheral vein in said human patient, said unit dose comprising from about .008 mg to 7.2 mg of [a]said recombinant FGF-2 or [an]said angiogenically active fragment or said angiogenically active mutein thereof.

32. (amended) The method of claim 31, wherein said recombinant FGF-2 has the amino acid sequence of SEQ ID NO: 2.

35. (twice amended) A method for providing a human patient with relief from symptoms of angina, comprising administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or an angiogenically active mutein thereof into one or more coronary vessels or into a peripheral vein in a human patient in need of relief from symptoms of angina, said unit dose comprising from about 0.008 mg to 7.2 mg of [a]said recombinant FGF-2 or [an]said angiogenically active fragment or said angiogenically active mutein thereof.

38. (amended) The method of claim 10, wherein said therapeutically effective amount of said recombinant FGF-2 or said angiogenically active fragment or said angiogenically active mutein thereof is administered by infusion.

44. (amended) A method for treating a human patient for coronary artery disease, comprising administering a therapeutically effective amount of a recombinant FGF-2 or an angiogenically active fragment or an angiogenically active mutein thereof by infusion into one or more coronary vessels or into a peripheral vein in a human patient in need of treatment for said coronary artery disease, said therapeutically effective amount being about 0.2 μg/kg to 48 μg/kg of patient weight.

46. (amended) The method of claim 45, further comprising the step of administering to said human patient about 10 U/kg to 80 U/kg of heparin within about 0 to 30 minutes prior to administering said recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or said angiogenically active mutein thereof.

47. (amended) The method of claim 46, wherein said therapeutically effective amount of [a]said recombinant FGF-2 of SEQ ID NO: 2 or [an]said angiogenically active fragment or said angiogenically active mutein thereof is administered into one or more coronary vessels.

48. (amended) The method of claim 47, wherein said therapeutically effective amount of [a]said recombinant FGF-2 of SEQ ID NO: 2 or [an]said angiogenically active fragment or said angiogenically active mutein thereof is about 24 μg/kg to 48 μg/kg.

49. (amended) The method of claim 46 wherein said therapeutically effective amount of [a]said recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or said angiogenically active mutein thereof is administered into a peripheral vein.

50. (amended) The method of claim 49, wherein said therapeutically effective amount of [a]said recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or said angiogenically active mutein thereof is about 18 μg/kg to 36 μg/kg.

51. (amended) A method for treating a human patient for coronary artery disease comprising, administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or an angiogenically active mutein thereof by infusion into one or more coronary vessels or into a peripheral vein in a human patient in need of treatment for coronary artery disease, said unit dose comprising from about .008 mg to 7.2 mg of [a]said recombinant FGF-2 or [an]said angiogenically active fragment or said angiogenically active mutein thereof.

52. (amended) The method of claim 51, wherein said recombinant FGF-2 has the amino acid sequence of SEQ ID NO: 2.

56. (amended) The method of claim 52, wherein said unit dose comprises 0.3 mg to 3.5 mg of [a]said recombinant FGF-2 of SEQ ID NO: 2 or [an]said angiogenically active fragment or said angiogenically active mutein thereof.

58. (amended) A method for inducing angiogenesis in a heart of a human patient, comprising administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or an angiogenically active mutein thereof by infusion into one or more coronary vessels or into a peripheral vein in a human patient in need of treatment for coronary artery disease, said unit dose comprising from about .008 mg to 7.2 mg of [a]said recombinant FGF-2 or [an]said angiogenically active fragment or said angiogenically active mutein thereof.

59. (amended) The method of claim 58, wherein said recombinant FGF-2 has the amino acid sequence of SEQ ID NO: 2.

62. (amended) A method for treating a human patient for a myocardial infarction, comprising administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or an angiogenically active mutein thereof by infusion into one or more coronary vessels or into a peripheral vein in said human patient, said unit dose comprising from about .008 mg to 7.2 mg of [a]said recombinant FGF-2 or [an]said angiogenically active fragment or said angiogenically active mutein thereof.

64. (amended) The method of claim 63, wherein said recombinant FGF-2 has the amino acid sequence of SEQ ID NO: 2.

65. (amended) A method for providing a human patient with relief from symptoms of angina comprising administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or an angiogenically active mutein thereof by infusion into one or more coronary vessels or into a peripheral vein in a human patient in need of relief from symptoms of angina, said unit dose comprising from about 0.008 mg to 7.2 mg of [a]said recombinant FGF-2 or [an] said angiogenically active fragment or said angiogenically active mutein thereof.